Vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial

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Abstract: BACKGROUND: In the treatment of vertebral compression fractures, vertebral body stenting with an expandable scaffold inserted before application of the bone cement was developed to impede secondary loss of vertebral height encountered in patients treated with balloon kyphoplasty. The purpose of this study was to clarify whether there are relevant differences between balloon kyphoplasty and vertebral body stenting with regard to perioperative and postoperative findings. METHODS: In a two-armed randomized controlled trial, patients with a total of 100 fresh osteoporotic vertebral compression fractures were treated with either balloon kyphoplasty or vertebral body stenting. The primary outcome was the post-interventional change in the kyphotic angle on radiographs. The secondary outcomes were the maximum pressure of the balloon tamp during inflation, radiation exposure time, perioperative complications, and cement leakage. RESULTS: The mean reduction (and standard deviation) of kyphosis (the kyphotic correction angle) was 4.5° ± 3.6° after balloon kyphoplasty and 4.7° ± 4.2° after vertebral body stenting (p = 0.972). The mean pressures were 24 ± 5 bar (348 ± 72 pounds per square inch [psi]) during vertebral body stenting and 16 ± 6 bar (233 ± 81 psi) during balloon kyphoplasty (p = 0.014). There were no significant differences in radiation exposure time.None of the patients underwent revision surgery, and postoperative neurologic sequelae were not observed. Cement leakage occurred at twenty-five of the 100 vertebral levels without significant differences between the two intervention arms (p = 0.230). Intraoperative material-related complications were observed at one of the fifty vertebral levels in the balloon kyphoplasty group and at nine of the fifty levels in the vertebral body stenting group. CONCLUSIONS: No beneficial effect of vertebral body stenting over balloon kyphoplasty was found among patients with painful osteoporotic vertebral fractures with regard to kyphotic correction, cement leakage, radiation exposure time, or neurologic sequelae. Vertebral body stenting was associated with significantly higher pressures during balloon inflation and more material-related complications.

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Vertebral Body Stenting Versus Kyphoplasty for the Treatment of Osteoporotic Vertebral Compression Fractures

A Randomized Trial

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Background: In the treatment of vertebral compression fractures, vertebral body stenting with an expandable scaffold inserted before application of the bone cement was developed to impede secondary loss of vertebral height encountered in patients treated with balloon kyphoplasty. The purpose of this study was to clarify whether there are relevant differences between balloon kyphoplasty and vertebral body stenting with regard to perioperative and postoperative findings.

Methods: In a two-armed randomized controlled trial, patients with a total of 100 fresh osteoporotic vertebral compression fractures were treated with either balloon kyphoplasty or vertebral body stenting. The primary outcome was the post-interventional change in the kyphotic angle on radiographs. The secondary outcomes were the maximum pressure of the balloon tamp during inflation, radiation exposure time, perioperative complications, and cement leakage.

Results: The mean reduction (and standard deviation) of kyphosis (the kyphotic correction angle) was 4.5° ± 3.6° after balloon kyphoplasty and 4.7° ± 4.2° after vertebral body stenting ($p = 0.972$). The mean pressures were 24 ± 5 bar (348 ± 72 pounds per square inch [psi]) during vertebral body stenting and 16 ± 6 bar (233 ± 81 psi) during balloon kyphoplasty ($p = 0.014$). There were no significant differences in radiation exposure time.

None of the patients underwent revision surgery, and postoperative neurologic sequelae were not observed. Cement leakage occurred at twenty-five of the 100 vertebral levels without significant differences between the two intervention arms ($p = 0.230$). Intraoperative material-related complications were observed at one of the fifty vertebral levels in the balloon kyphoplasty group and at nine of the fifty levels in the vertebral body stenting group.

Conclusions: No beneficial effect of vertebral body stenting over balloon kyphoplasty was found among patients with painful osteoporotic vertebral fractures with regard to kyphotic correction, cement leakage, radiation exposure time, or neurologic sequelae. Vertebral body stenting was associated with significantly higher pressures during balloon inflation and more material-related complications.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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A commentary by Christoph J. Siepe, MD, PhD, is linked to the online version of this article at jbjs.org.

About 1.4 million patients are affected by clinical vertebral compression fractures worldwide every year[1]. With demographic shifts in age[2] and sex[3], the number of these fractures will be increasing[4]. Thus, vertebral compression fractures represent a major health-care problem of increasing impact[5].

Although most of these fractures are asymptomatic, the resulting loss of vertebral height leads to spinal sagittal imbalance and sequential vertebral compression fractures in osteoporotic patients. Progressive spinal deformity may cause respiratory and abdominal restrictions. The mortality rate after the diagnosis of a vertebral compression fracture is approximately twice as high as that for controls[6]. Vertebroplasty was introduced as an alternative to bed rest and mobilization along with analgesic therapy in 1997[7]. However, recent publications cast doubt on the effect of classic vertebroplasty, at least on older fractures, as the inclusion criterion in some early studies was "pain less than twelve months."[8,9] Thus, vertebroplasty was refined by the use of inflatable balloon tamps (percutaneous balloon kyphoplasty)[10-12]. Using a balloon resulted in greater height restoration[13] and less cement leakage as compared with these parameters following vertebroplasty[14].

In theory, deflation of the balloon can be followed by secondary loss of the initial reduction with a decrease in vertebral height[15]. This concern led to the development of an expandable scaffold that is inserted before the cement to impede secondary loss of vertebral height (vertebral body stenting)[16-18]. To our knowledge, vertebral body stenting has not been evaluated in vivo; it has only been tested against balloon kyphoplasty in cadaver specimens[17]. The advantage of vertebral body stenting remains theoretical, and the optimal treatment of this patient population is still debated. The purpose of this prospective randomized trial was to clarify whether there are differences between balloon kyphoplasty and vertebral body stenting with regard to relevant perioperative and postoperative findings.

Materials and Methods

This study was a prospective randomized trial conducted at a single trauma center of maximum care (Level I) in Switzerland. The study was approved by our institutional review board (Kantonale Ethikkommission Zürich, Ref. No. 2009-0117-4), and written informed consent was received from all enrolled patients.

Patients

Patients with one or more osteoporotic vertebral compression fractures of the thoracic, thoracolumbar, or lumbar spine were eligible (Fig. 1). Osteoporotic fractures were defined as fractures that occurred spontaneously or as a result of minimal trauma from day-to-day activities[19]. Fractures were classified according to the AO classification[20] on preoperative radiographs and computed tomography

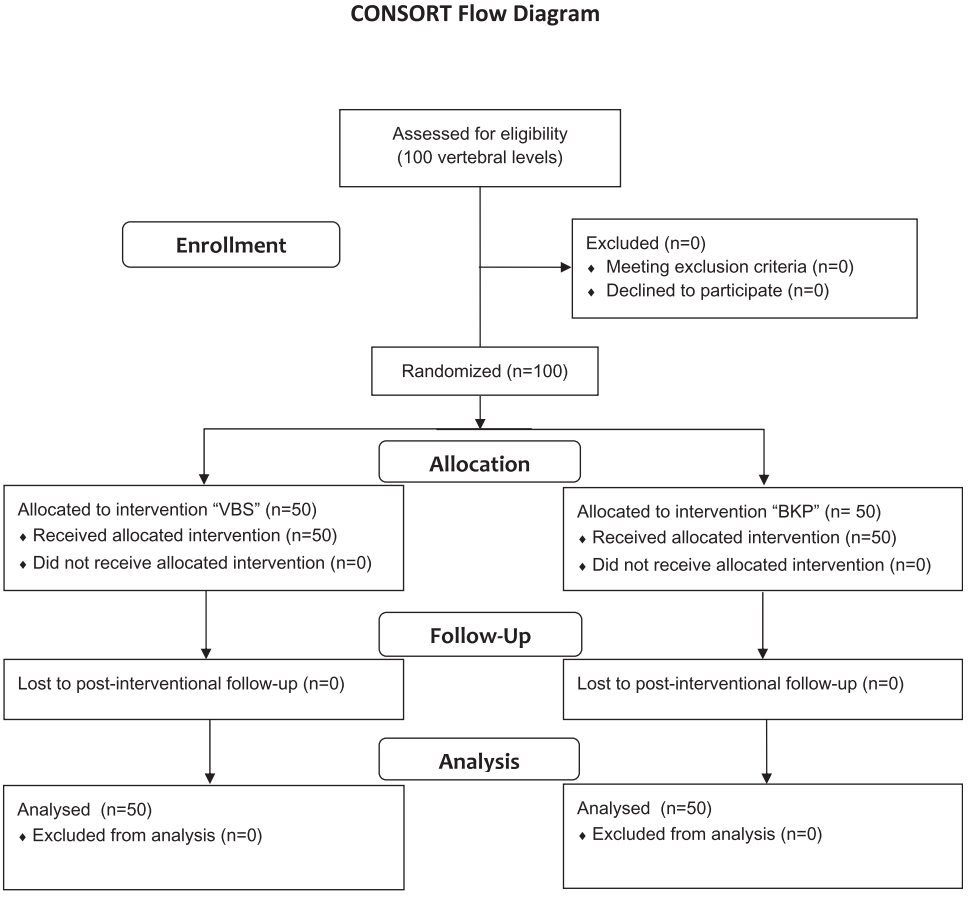

Fig. 1

Algorithm for patients included in the study. VBS = vertebral body stenting and BKP = balloon kyphoplasty.

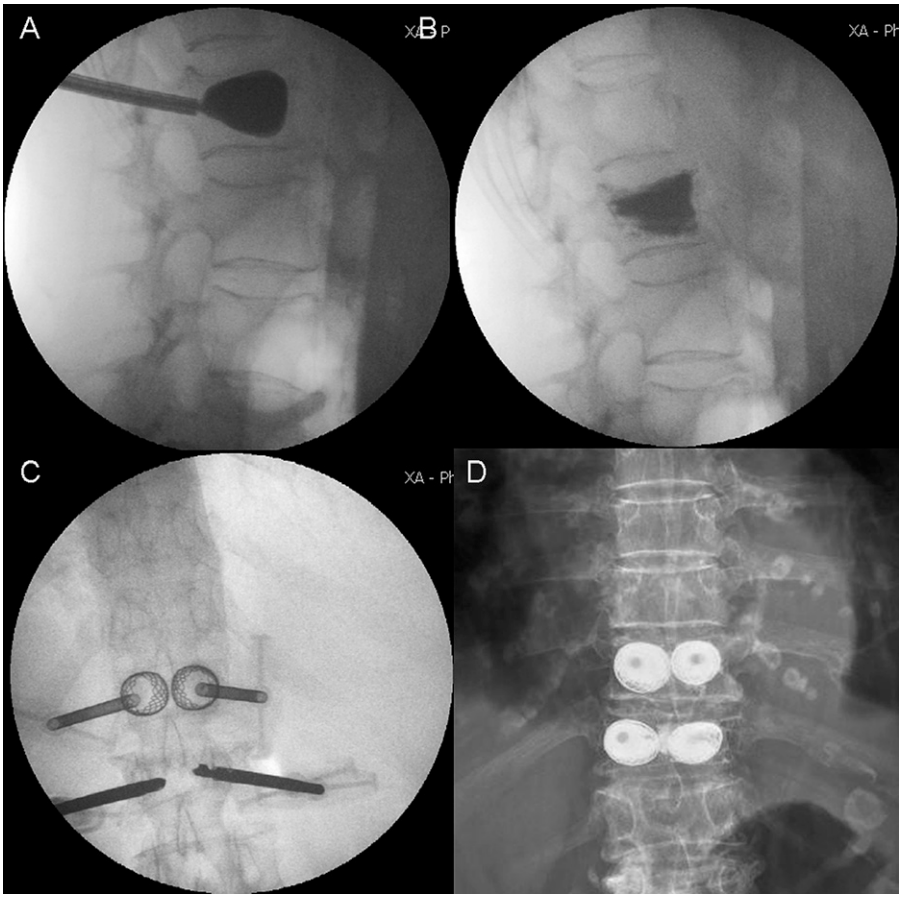

Fig. 2

Balloon kyphoplasty (A and B) and vertebral body stenting (C and D) during (A and C) and after (B and D) intervention.

(CT) scans as described previously[21], and patients with A1.1, A1.2, A1.3, and A3.1 fractures types were included. Additional inclusion criteria were fresh fractures as demonstrated on magnetic resonance imaging (MRI) with use of transverse short tau inverted recovery (STIR) sequences as described previously[22,23] and patients with marked pain. Exclusion criteria were pregnancy, high-energy trauma, polytrauma, previous major spine surgery within one year prior to admission, bone metastasis, and additional posterior spinal instrumentation. Diagnostic evaluation included physical examination, preoperative and postoperative anteroposterior and lateral radiographs, CT (Somatom Definition; Siemens, Munich, Germany; 128-slice dual-source CT; 120 kV, 210 mA), and MRI (Siemens Symphony, Espree, or Avanto; Siemens Medical Solutions, Erlangen, Germany) including STIR sequences to determine the age of fractures.

Randomization

Randomization was performed blockwise for five blocks of twenty patients (ten in arm A and ten in arm B) with use of a web-based computerized algorithm (www.randomizer.org). The randomization items were not the 100 patients but the 100 vertebral levels. If more than one level was affected in a single patient, all fractured vertebrae (levels) were allocated to the same intervention (A). The given randomization scheme was then completed for the subsequent patient(s) by balancing leaped interventions B. This was done to avoid different interventions in the same patient. We used blocks of only ten per arm to be able to use collected data in case the study was aborted as a result of unexpected complications.

Interventions

All interventions were conducted in the presence and under the supervision of one of us (C.M.L.W.). Both balloon kyphoplasty and vertebral body stenting were established procedures at our institution. The procedures were performed through a percutaneous transpedicular approach with use of Jamshidi needles and working cannulas as described previously[10,12,18]. After a canal was drilled into the vertebral body, either a balloon kyphoplasty (KyphX-Systems; Kyphon, Medtronic, Minneapolis, Minnesota) or a vertebral body stenting (Synthes, Oberdorf, Switzerland) system was used according to the described randomization scheme (Fig. 2). Either two balloons (for balloon kyphoplasty) or two stents (for vertebral body stenting) were placed below the collapsed vertebral end plate as seen on a fluoroscopic lateral view. The balloon tamps were inflated slowly and under fluoroscopic and continuous manometric control. A maximum pressure of 28 bar (400 pounds per square inch [psi]) was allowed according to both systems' manufacturer manual. If the stent did not open under 28 bar (400 psi) during the vertebral body stenting, the pressure was carefully increased to a maximum of 34 bar (500 psi). Inflation was stopped when either appropriate reduction or complete balloon expansion within the vertebral body was achieved or a complication occurred. (i.e., rupture of the balloon). For balloon kyphoplasty, polymethylmethacrylate cement (KyphX HV-R; Kyphon, Medtronic) was prepared and viscosity was considered to be optimal when at least a 7-cm vermicular cement extrusion could be pressed out of the syringe and stay attached. For vertebral body stenting, the viscosity of the cement (Vertecem V+ Cement Kit, VBS; Synthes) was determined with use of the manufacturer's viscometer (Viscosafe Viscometer; Synthes). The balloons were removed, and the vertebral body was filled with cement with bone-filler cannulas and stylets for balloon kyphoplasty (KyphX Express Bone Filler Device; Kyphon, Medtronic) and syringes for vertebral body stenting (Vertecem V+ Syringe Kit, VBS; Synthes). Filling was performed under repetitive fluoroscopic control in two projections until the cement reached the posterior border or leakage was seen.

TABLE I Kyphotic Correction, Balloon Pressure, and Radiation Time

	Balloon Kyphoplasty*	Vertebral Body Stenting*	P Value
Kyphotic correction angle *(°)*	4.5 ± 3.6	4.7 ± 4.2	0.972
Balloon tamp pressure *(psi)*	233 ± 81	348 ± 72	0.014†
Radiation time *(s)*	96 ± 66	116 ± 42	0.462

*Data are expressed as the mean and standard deviation. †Significant at a level of $p < 0.05$.

Measurements and Complications

The primary outcome was the post-interventional change in the kyphotic angle. Vertebral kyphosis was measured by determining the wedge angle[24] on preoperative and postoperative radiographs of every patient with use of a Picture Archiving and Communication System (PACS)-implemented goniometer. Intraoperatively, the maximum pressures of the balloon tamps during inflation and the total radiation exposure time were recorded. A CT scan was added when a patient had suspected cement outside the vertebral body as seen on the postoperative radiograph or had intraoperative complications. Intraoperative cement leaking and material-related complications or failure were documented on a case report form. All events were cumulated for each level. Only one complication was recorded if it occurred bilaterally in one vertebra, and two complications were recorded if they occurred at two levels in the same patient. Material-related complications outside the patient were not documented. Cement leakage was defined as "minor" (paravertebral) or "major" (into the venous plexus, into the spinal canal, behind the anterior longitudinal ligament, or into the intervertebral disc space).

Postoperatively, a full physical examination with a focus on neurologic sequelae was done.

Statistical Analysis

Sample-size calculation was performed with use of PS: Power and Sample Size Calculations 3.0 (alpha error: 0.05)[25]. The final sample size of 100 vertebral levels (group ratio, 1:1; power, 0.95) was based on a proposed difference in the change in the kyphotic angle of 2.2° ± 3.0° between balloon kyphoplasty and vertebral body stenting as shown in vitro by Rotter et al.[17].

Data are expressed as the mean and standard deviation. The primary analysis includes all vertebral levels that were randomized. Patient-based comparisons were made between treatment arms with use of Mann-Whitney U tests (continuous data) or chi-square tests (categorical variables).

To account for clustering of vertebral levels within patients, logistic regression analysis with the treatment group as a dependent variable and a robust sandwich estimator for standard errors allowing for intragroup correlation (Stata command logit with option vce [cluster patient]) was used. Stata 11.2 (StataCorp, College Station, Texas) was used for these analyses. All reported p values are two-sided with a level of significance of 0.05. Statistical analyses were performed by an institutional statistician.

Source of Funding

There was no external funding source for this investigation.

Results

Patients

Sixty-five patients with a mean age (and standard deviation) of 70 ± 13 years were enrolled. Forty women (mean age, 73 ± 10 years) and twenty-five men (mean age, 63 ± 14 years) with a total of 100 involved vertebral levels (mean, 1.5 levels/patient; interquartile range, one to two levels/patient) were treated. Thirty-two (49%) of the sixty-five patients underwent surgery under general anesthesia and thirty-three (51%), under local anesthesia. The distribution of fracture morphology according to the AO classification was sex-dependent ($p = 0.015$), with type-A3.1 fractures being more frequent in women and type-A1.1 fractures being more frequent in men. There were no significant differences between the intervention arms regarding the patients' baseline characteristics (see Appendix).

Kyphotic Correction

The mean reduction of the kyphosis (kyphotic correction angle) was 4.5° ± 3.6° (range, 0.0° to 14.3°) after balloon kyphoplasty and 4.7° ± 4.2° (range, 0.0° to 20.0°) after vertebral body stenting. The median reduction of the kyphosis was 4.1° after balloon kyphoplasty and 3.7° after vertebral body stenting (Fig. 3). These differences were not significant (Table I).

Pressure and Radiation Exposure Time

The mean pressures were 26 bar (371 psi) in men and 22 bar (324 psi) in women during vertebral body stenting and 18 bar (255 psi) and 15 bar (217 psi), respectively, during balloon kyphoplasty (see Appendix). There was a significant difference

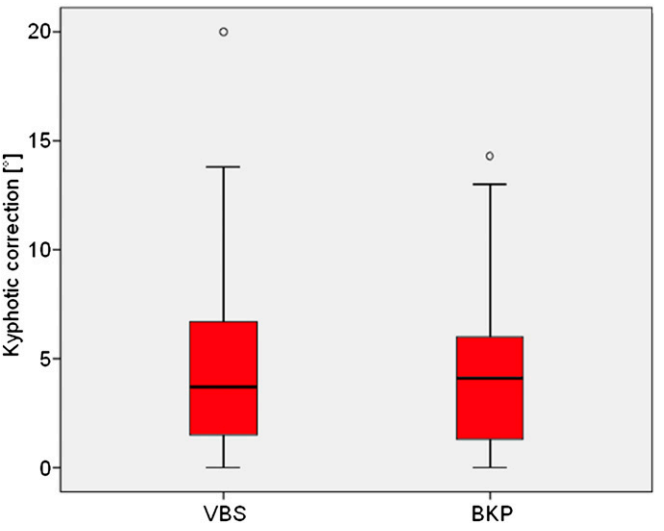

Fig. 3

Kyphotic correction. VBS = vertebral body stenting and BKP = balloon kyphoplasty. The bottom and top of the boxes indicate the first and third quartiles, the bars indicate the range, the horizontal bars within the boxes indicate the median, and the circles indicate outliers.

TABLE II Complications

	Balloon Kyphoplasty*	Vertebral Body Stenting*	P Value	Total*
No. of levels	50	50		100
Cement leakage			0.230	
None	40 (80%)	35 (70%)		75 (75%)
Minor	6 (12%)	10 (20%)		16 (16%)
Major	4 (8%)	5 (10%)		9 (9%)
Material-related complications			0.043†	
Cannula	0 (0%)	5 (10%)		5 (5%)
Balloon	1 (2%)	1 (2%)		2 (2%)
Stent	—	3 (6%)		3 (3%)
Neurologic sequelae	0	0	—	0
Total complications	11 (22%)	24 (48%)	0.013†	35 (35%)

*Data are expressed as the number with the percentage in parentheses. †Significant at a level of $p < 0.05$.

between the two intervention arms ($p = 0.014$) (Table I). Vertebral body stenting was associated with noticeably higher pressures during balloon inflation (range, 12 to 34 bar [180 to 500 psi]) compared with balloon kyphoplasty (range, 5 to 28 bar [67 to 400 psi]).

There were no significant differences in radiation exposure time between the two intervention arms.

Complications

None of the patients underwent revision surgery as a result of complications of the primary intervention. There were no postoperative neurologic sequelae. Cement leakage occurred at 25% of the 100 levels without significant differences between the two intervention arms ($p = 0.230$; Table II and Fig. 4). In total, nine cases of major cement leakage were observed: six into the paravertebral veins (three in the vertebral body stenting group and three in the balloon kyphoplasty group), one behind the anterior longitudinal ligament (vertebral body stenting), one into the cranial intervertebral disc space (balloon kyphoplasty), and one into the spinal canal (vertebral body stenting).

Intraoperative material-related complications occurred at ten of the 100 levels. Of the fifty balloon kyphoplasties, one (2%) was associated with a balloon rupture. In contrast, nine (18%) of the fifty vertebral body stenting procedures were associated with a material-related complication, including failure of the working cannulas, incomplete or no opening of the stent, and balloon rupture (Table II).

While the total number of complications was significantly higher in the vertebral body stenting group ($p = 0.013$), there was no significant difference between the two intervention arms after elimination of the effect of material failure (i.e., when only cement leakage and neurologic sequelae were considered).

An analysis of the influence of single and multiple-level procedures (see Appendix) on the outcome showed no significant effect on kyphotic reduction ($p = 0.411$). However, single-level procedures were associated with significantly more instances of cement leakage than multilevel procedures ($p = 0.001$).

In addition, the anatomical fracture level (thoracic, thoracolumbar, or lumbar) had no influence on the occurrence of cement complications ($p = 0.634$).

Several material-related complications occurred outside the patient. These were mainly breakage of the trocar's plastic tip, impeding introduction of the system. Since these material complications did not affect the primary outcome, they were not documented according to the study protocol.

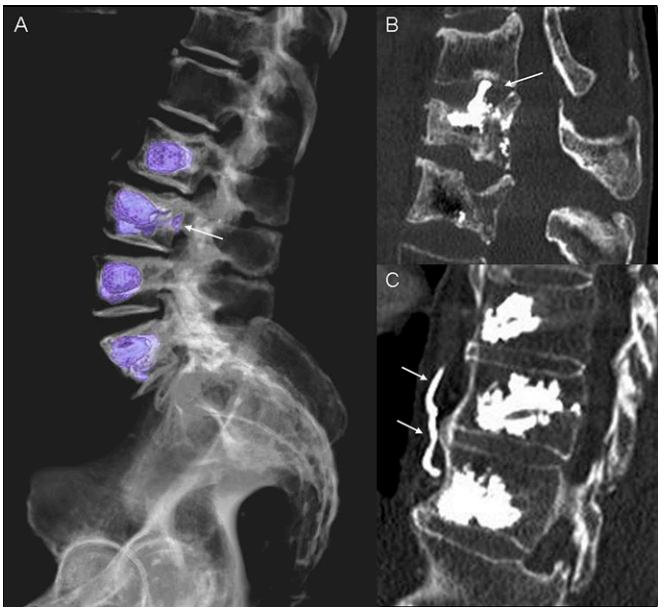

Fig. 4

Cement extrusion (arrows), including paravertebral extrusion (A), extrusion into the cranial intervertebral disc space (B), and extrusion behind the anterior longitudinal ligament (C).

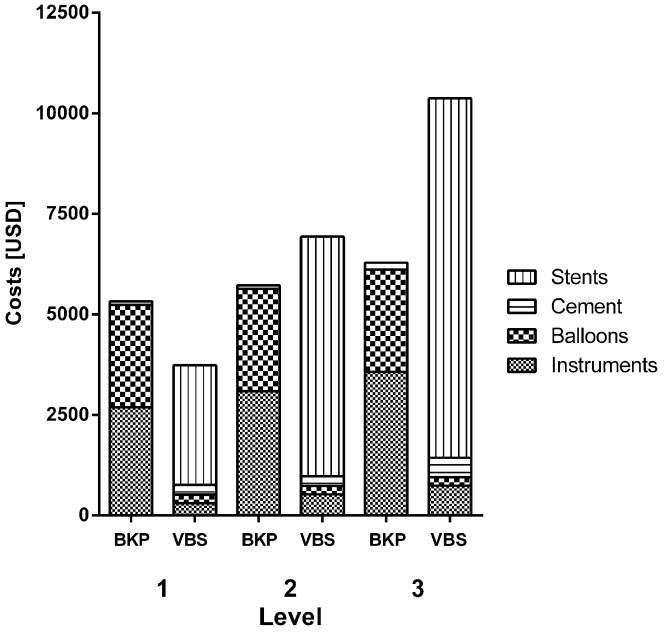

Fig. 5

Material costs according to the manufacturers for one, two, and three levels. BKP = balloon kyphoplasty, VBS = vertebral body stenting, and USD = U.S. dollars.

Costs

The material costs (in Switzerland in 2010) for one vertebral level were approximately $3750 (U.S. dollars) for vertebral body stenting and $5300 for balloon kyphoplasty. When two or three levels were treated in the same patient, these costs were $6950 (two levels) and $10,400 (three levels) for vertebral body stenting and $5700 and $6300 for balloon kyphoplasty (Fig. 5). For both systems, one balloon was used several times in the same patient (unless there was balloon breakage) even if more than one level was treated.

Discussion

This clinical randomized trial showed no beneficial effect of vertebral body stenting over balloon kyphoplasty with regard to the amount of kyphosis correction, radiation exposure time, or cement leakage among patients with painful osteoporotic vertebral fractures. Vertebral body stenting was associated with significantly higher pressures during balloon inflation and more material-related complications.

Complications

Cement leakage was observed at 20% of the vertebral levels treated with balloon kyphoplasty and 30% of those treated with vertebral body stenting; this difference was not significant. Reported leakage rates have ranged from 8.6% to 27.8%[11,12,14,26,27] for balloon kyphoplasty. In most of these studies, the investigators did not use CT to exclude or verify suspected cement extrusion, which may explain the higher leakage detection rate in our population. The only available study related to leakage following vertebral body stenting[18] of which we are aware revealed a cement leakage rate of 10%. That study, however, included traumatic fractures and the included osteoporotic fractures were all classified as type A1.1[18]. In addition, Klezl et al.[18] did not use Vertecem V+ cement as suggested by the manufacturer of the vertebral body stenting system; instead, they used the more viscous KyphX HV-R. This is an off-label use that raises the question of whether the viscosity of Vertecem V+ itself may be the cause of cement leakage.

It is important to recognize that cement leakage is primarily a radiographic finding that is not always followed by clinical symptoms. Although sequential fractures have been described after cement leakage into the intervertebral disc space[28], this was not observed in the one patient in our study who had cement leakage into the intervertebral disc space. Nonetheless, we believe that balloon kyphoplasty and vertebral body stenting should be reserved for centers that are able to handle possible complications such as spinal cord compression.

Vertebral body stenting was associated with higher pressures during balloon inflation. In two cases, the vertebral body stents did not open at all. We tried to get them to expand intraoperatively by exceeding the opening pressures suggested by the manufacturer. Unfortunately, this led to balloon rupture rather than stent expansion.

Kyphotic Correction

Balloon kyphoplasty is known to result in a kyphotic correction of 4° to 7°[26,28], and the only clinical study of vertebral body stenting of which we are aware demonstrated a kyphotic correction of 4.5° in osteoporotic patients[18]. The kyphotic correction observed in our two intervention arms is consistent with previously published clinical data.

Vertebral body stenting did not achieve the initial goals of avoiding secondary loss of vertebral height and less cement leakage in our study. One important reason for this was that the stents frequently failed to open properly (see Appendix). This led to insufficient expansion of the balloon tamps with unsatisfactory fracture reduction and was followed by increased pressures during inflation and in some cases by balloon rupture. It was stressed previously that precise positioning of the two stents is crucial in vertebral body stenting[18].

Both tested procedures had been established for at least one year at our hospital before the present trial was begun. It therefore is unlikely that the results were due to a learning curve[29]. However, precise positioning of the stents can be difficult in some fractures, and the capacity to tolerate variance is obviously smaller with vertebral body stenting than it is with balloon kyphoplasty. Once the stent is inserted or even expanded, repositioning or removal is very difficult. Salvage procedures such as eggshell techniques are not possible.

Costs

We did not evaluate the individual costs per patient; instead we examined the standard general material costs per level. Considering the 1.5 levels per patient treated in the present study, we found no remarkable difference in costs between the two systems. One has to take into account the many material-related

complications that led to the use of multiple sets in the same patient as this increased the costs per patient. In addition, it has to be considered that, although no substantial differences in costs were found, vertebral body stenting was compared with a balloon kyphoplasty system (KyphX-Systems) that is rather expensive[30].

A limitation of this trial is that it was not possible to blind both treatment and measurements because of the obvious characteristics of the implants. However, as not one eligible patient was excluded and crossovers were not possible, selection bias was avoided and intention-to-treat analysis was guaranteed.

The present study focused on perioperative and postoperative events. Therefore, no statements regarding potential effects on the clinical outcome can be made. However, we could not confirm that adding a vertebral stent avoided secondary loss of vertebral height, and without achieving this goal a clinical effect is at least questionable.

Patients with fresh osteoporotic fractures as demonstrated with MRI STIR sequences accompanied by severe pain were included in this study. Because of the population's characteristics (age and multiple/repetitive falls), it is often difficult or impossible to determine the true age of osteoporotic fractures on the basis of the patient's history; thus, MRI is useful to exclude advanced consolidation. In contrast, one may assume that studies of therapies for vertebral compression fractures without prior MRI sometimes include old fractures[31].

Even with use of MRI, inclusion of old fractures was possible. If vertebral body stenting was applied to fractures beyond an early stage, that might explain higher pressures required for balloon opening, which would explain higher rates of material-related complications and cement leakage. This would lead to the recommendation of using vertebral body stenting only in the immediate posttraumatic period or within a few days after the onset of symptoms. However, to our knowledge, this study is the first interventional vertebral compression fracture trial in which MRI was used for every patient. Trials using a more precise determination of fracture age have not yet been published.

In conclusion, we found no beneficial effect of vertebral body stenting over balloon kyphoplasty with regard to kyphotic correction, cement leakage, radiation exposure time, or neurologic sequelae among patients with painful osteoporotic vertebral fractures. Vertebral body stenting was associated with significantly higher pressures during balloon inflation and remarkably more material-related complications.

Appendix

eA Tables showing patients' baseline characteristics and number of levels treated per patient as well as figures showing maximum intraoperative balloon pressure and failure of stent opening are available with the online version of this article as a data supplement at jbjs.org. ■

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